### PATENT COOPERATION TREATY

# INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY (Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44bis)

Applicant's or agent's file reference 37697-0101	FOR FURTHER ACTION	See item 4 below				
International application No. PCT/US2005/001888	International filing date (day/month/year) 21 January 2005 (21.01.2005)	Priority date (day/month/year) 23 January 2004 (23.01.2004)				
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237 `						
Applicant MASSACHUSETTS GENERAL HO	DSPITAL	1				

1.	<ol> <li>This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 bis.1(a).</li> </ol>						
2.	In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference						
	to the international preliminary	report on patentability (Chapt	er 1) instead.				
3.	3. This report contains indications relating to the following items:						
	Box No. I	Basis of the report					
	Box No. II Priority						
	Box No. III  Non-establishment of opinion with regard to novelty, inventive step and industrial applicability						
	Box No. IV Lack of unity of invention						
	Box No. V	Box No. V  Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement					
ĺ	Box No. VI	o. VI Certain documents cited					
	Box No. VII	No. VII Certain defects in the international application					
	Box No. VIII	Certain observations on the international application					
4.	4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44bis.3(c) and 93bis.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44bis.2).						
	•	<del>-</del>					
	Date of issuance of this report 24 July 2006 (24.07.2006)						
The International Bureau of WIPO 34, chemin des Colombettes			Authorized officer				
1211 Geneva 20, Switzerland			Athina Nickitas-Etienne				
Facsin	Facsimile No. +41 22 338 82 70 e-mail: pt04@wipo.int						

Form PCT/IB/373 (January 2004)

### PATENT COOPERATION TREATY

NTERNATIONAL SEARCHING AUTH	ORITY		PCT	REC'D 2 7 JUN 200			
To: JOHN P, ISACSON		WIPO					
HELLER EHRMAN WHITE & MCAULIFFE LLP							
SUITE 300 1666 K STREET, NW		WR	ITTEN ÒPINION OI ONAL SEARCHING	F THE AUTHORITY			
WASHINGTON, DC 20006-1228		MIEKNAIN					
			(PCT Rule 43 <i>bis</i> .1)				
•	·	Date of mailing (day/month/year 24 JUN 2003					
Applicant's or agent's file reference		FOR FURTHER ACTION					
37697-0101	·	See paragraph 2 below					
International application No.	International filing date (c	(day/month/year) Priority date (day/month/year)					
PCT/US05/01888	21 January 2005 (21.01.2	005)	23 January 2004 (23.01	.2004)			
International Patent Classification (IPC)		on and IPC					
IPC(7): A61F 2/38 and US C1.: 623/20. Applicant	21	<del></del>					
MASSACHUSETTS GENERAL HOSP	ITAL						
1. This opinion contains indications re	lating to the following items	<b>s:</b> ,					
Box No. I Basis of the	e opinion		.,				
Box No. II Priority	•						
Box No. III Non-establ	ishment of opinion with reg	ard to novelty, inv	entive step and industrial	applicability			
Box No. IV Lack of un	ity of invention		·.				
Box No. V  Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement							
	cuments cited						
	fects in the international ap	plication					
	servations on the internatio		•				
BOX NO. VIII CERTAIN OU	act various on the internation			ļ			
2. FURTHER ACTION  If a demand for international preli		a this oninion wil	l he considered to he a v	written opinion of the			
If a demand for international preliminary Examini Authority other than this one to be that written opinions of this International	ing Authority ("IPEA") ex the IPEA and the chosen l	cept that this doe PEA has notified t	he International Bureau u	applicant chooses and t			
If this opinion is, as provided about IPEA a written reply together, we mailing of Form PCT/ISA/220 or leading to the provided about 1985 and 1985 are represented in the provided about 1985 and 1985 are represented in the provided about 1985 are represented about 1985 are represen	here appropriate, with am before the expiration of 22	endments, before	the expiration of 3 mon	mis morn are date or			
For further options, see Form PCT	C/ISA/220.	•					
3. For further details, see notes to Fo	rm PCT/ISA/220.		. ·				
Name and mailing address of the ISA/	US .	Authorized office	er Brust	North.			
Mail Stop PCT, Atm: ISA/US Commissioner for Patents	,	Thomas C. Bar	rett Grand	for			
P.O. Box 1450 Alexandria, Virginia 22313-1450		Telephone No.	703 308 0850.				
Facsimile No. (703) 305-3230 Form PCT/ISA/237 (cover sheet) (Janua	ry 2004)	1	<u> </u>				
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# WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US05/01888

Box No	o. I Basis of this o	pinion						
l. With it was	regard to the languages filed, unless otherwis	se indicated under th	is item.					
	This opinion has been which is the language	n established on the e of a translation fur	basis of a trans	slation from purposes of i	the original international	language into l search (under	the following Rules 12.3 ar	nd 23.1(b)).
2. With claim	regard to any nucle ed invention, this opin	otide and/or amin nion has been establi	o acid sequen shed on the bas	ce disclosed sis of:	in the inte	rnational appl	ication and ne	ecessary to the
a.	type of material	•						
	a sequence list	ing					٠	
	table(s) related	i to the sequence list	ting			,		-
b.	format of material	•						
	in written form	nat						
	in computer re	eadable form						
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	•	international applica	tion as filed.	٠				
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3.	filed or furnished t	case that more than the required stateme iled or does not go b	nts that the info	ormation in t	the subseque	ent or addition:	ai copies is ide	hereto has been entical to that in
4. Addi	itional comments:							•
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# WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

Form PCT/ISA/237 (Box No. V) (January 2004)

International application No. PCT/US05/01888

Box No. V Reasoned statement under Rule	2 43 bis.1(a)(i)	with regard	l to novelty,	inventive	step or ind	ustrial
applicability; citations and expla	anations supp	orting such s	tatement			·
1. Statement						
	Claims	NONE				YES
Novelty (N)	Claims					NO
		•				
Inventive step (IS)	Claims					YES NO
	Claims	1-71	·			
Industrial applicability (IA)	Claims	1-71				YES
mannin appropriate (v. 1)		NONE				NO
					<u> </u>	
2. Citations and explanations:	•					
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conting out they much to out the mine of these amounts.	•					
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Claims 1-71 meet the criteria set out in PCT Article can be made or used in industry.	ie 33(4), and thi	us have industi	a applicabili	y occause	me subject ma	unor ciamineu
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P.B.5818 - Patentlaan 2 2280 HV Rijswijk (ZH) (070) 3 40 20 40 FAX (070) 3 40 30 16 Europäisches Patentamt European Patent Office Office européen des brevets

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**EPO Customer Services** 

Tel.: +31 (0)70 340 45 00

Date

19.06.06

Reference

Application No./Patent No.

05705975.0 - 2310 PCT/US2005001888

Applicant/Proprietor

MASSACHUSETTS GENERAL HOSPITAL

### Entry into the European phase before the European Patent Office

These notes describe the procedural steps required for entry into the European phase before the European Patent Office (EPO). You are advised to read them carefully: fallure to take the necessary action in time can lead to your application being deemed withdrawn.

- 1. The above-mentioned international patent application has been given European application No. **05705975.0**.
- Applicants without a residence or their principal place of business in an EPC contracting state may themselves initiate European processing of their international applications, provided they do so before expiry of the 31st month from the priority date (see also point 6 below).

During the European phase before the EPO as designated or elected Office, however, such applicants must be represented by a professional representative (Arts. 133(2) and 134(1), (7) EPC).

Procedural acts performed after expiry of the 31st month by a professional representative who acted during the international phase but is not authorised to act before the EPO have no legal effect and therefore lead to loss of rights.

Please note that a professional representative authorised to act before the EPO and who acted for the applicant during the international phase does not automatically become the representative for the European phase. Applicants are therefore strongly advised to appoint in good time any representative they wish to initiate the European phase for them; otherwise, the EPO has to send all communications direct to the applicant.

- 3. Applicants with a residence or their principal place of business in an EPC contracting state are not obliged to appoint, for the European phase before the EPO as designated or elected Office, a professional representative authorised to act before the EPO.
  However, in view of the complexity of the procedure it is recommended that they do so.
- 4. Applicants and professional representatives are also strongly advised to initiate the European phase using EPO Form 1200 (available free of charge from the EPO). This however is not compulsory.

- Date
  - 5. To enter the European phase before the EPO, the following acts must be performed. (N.B.: Failure validly to do so will entail loss of rights or other adverse legal consequences.)
    - 5.1 If the EPO is acting as designated or elected Office (Arts. 22(1)(3) and 39(1) PCT respectively), applicants must, within 31 months from the date of filing or (where applicable) the earliest priority date:
      - a) Supply a translation of the international application into an EPO official language, if the International Bureau did not publish the application in such a language (Art. 22(1) PCT and R. 107(1)(a) EPC).
        If the translation is not filed in time, the international application is deemed withdrawn before the EPO (R. 108(1) EPC).
        This loss of rights is deemed not to have occurred if the translation is then filed within a two-month grace period as from notification of an EPO communication, provided a surcharge is paid at the same time (R. 108(3) EPC).
      - b) Pay the national basic fee (EUR 170,00) and, where a supplementary European search report has to be drawn up, the search fee (EUR 720,00; R. 107(1)(c) and (e) EPC).
      - c) If the time limit under Article 79(2) EPC expires before the 31-month time limit, pay the designation fee (EUR 80,00) for each contracting state designated (R. 107(1)(d) EPC).
      - d) If the time limit under Article 94(2) EPC expires before the 31-month time limit, file the written request for examination and pay the examination fee (EUR 1490,00; R. 107(1)(f) EPC).
      - e) Pay the third-year renewal fee (EUR 400,00) if it falls due before expiry of the 31-month time limit (R. 107(1)(g) EPC).

If the fees under (b) to (d) above are not paid in time, or the written request for examination is not filed in time, the international application is deemed withdrawn before the EPO, or the contracting-state designation(s) in question is (are) deemed withdrawn (R. 108(1) and (2) EPC). However, the fees may still be validly paid within a two-month grace period as from notification of an EPO communication, provided the necessary surcharges are paid at the same time (R. 108(3) EPC). For the renewal fee under (e) above, the grace period is six months from the fee's due date (Art. 86(2) EPC).

For an overview of search and examination fees, see OJ EPO 11/2005, 577 and 03/2006.

- 5.2 If the application documents on which the European grant procedure is to be based comprise more then ten claims, a claims fee is payable within the 31-month time limit under Rule 107(1) EPC for the eleventh and each subsequent claim (R. 110(1) EPC). The fee can however still be paid within a one-month grace period as from notification of an EPO communication pointing out the failure to pay (R. 110(2) EPC).
- 6 If the applicant had a representative during the application's international phase, the present notes will be sent to the representative, asking him to inform the applicant accordingly.

All subsequent communications will be sent to the applicant, or - If the EPO is informed of his appointment in time - to the applicant's European representative.

7. For more details about time limits and procedural acts before the EPO as designated and elected Office, see the EPO brochure

How to get a European patent Guide for applicants - Part 2 PCT procedure before the EPO - "Euro-PCT"

This brochure, the list of professional representatives before the EPO, Form 1200 and details of the latest fees are now all available on the Internet under

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11 JUL 2006

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